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FETAL MEDICINE UPDATE: Specialized care reduces HIV fetal transmission

By Stephen Rothman

Drug compliance, more support, helped ensure healthier babies

MIAMI BEACH, FLA. - The risk of mother-to-child HIV transmission during vaginal or cesarean delivery is negligible if the mother's viral load has been cut to undetectable levels and she receives specialized care.

"This is our opinion and I think we can guarantee it 100%," said Dr. Gina Hanna, an assistant professor of obstetrics and gynecology in the division of maternal/fetal medicine at Johns Hopkins University in Baltimore.

Dr. Hanna and colleagues reported on an analysis of HIV-infected women who gave birth in the university's hospital between January 1997 and June 1999.

"With an intensified effort, we obtained better compliance from the expectant mother with her drug regimen - leading to better outcomes than for women who received only standard care," said Dr. Edith Gurewitsch, assistant professor of obstetrics and gynecology at Johns Hopkins.

The team was composed of three physicians with specialties in maternal and fetal medicine and one ob/gyn with expertise in HIV in women.

The women in the study delivered after more than 24 weeks gestation - 48 received care through the intensified program and 16 received standard care.

The specialized care group had one fetal death to a woman with pneumocystis carinii pneumonia and one intrapartum death to a woman who had unexplained severe bradycardia. "The placenta and cord placement were abnormal so we do not think the death was HIV-related," Dr. Hanna said.

There was no perinatal HIV transmission among women in the specialized care group - of whom 35 had vaginal deliveries and 13 had C-sections.

But in the standard care group, there were two babies (12.5%) - one delivered by C-section and one vaginally - that ultimately tested positive for HIV.

Dr. Hanna said the zero transmission in the specialized care group is a "significant

finding."

Babies were considered free of HIV if they had two negative results of serum quantitative HIV ribonucleic acid by polymerase chain reaction, one month apart.

Dr. Gurewitsch said women in the special program have more frequent scheduled visits, running 30 to 45 minutes rather than the standard 15 minutes. "We discuss issues including whether they have told their partner about their HIV status and who will care for the child should she die prematurely. We also discuss the importance of adhering to their medical regimen.

"These patients are also seen by peer counsellors - some of whom are HIV positive - who accompany them for such things as home visits and come and stay with them during labour."

The team meets biweekly to review the patients.

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Glossary

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Index: M# - MF MG - MT MU - MZ

- **Maternal-fetal Transmission:** SFAF
  see vertical transmission.
  - **Vertical Transmission (Perinatal Transmission, Maternal-fetal Transmission):** SFAF
    transmission from a mother to a fetus or newborn. Vertical transmission may occur in utero (in the womb), intrapartum (during birth) or postpartum (via breast-feeding). Contrast with horizontal transmission.

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AZT APPROVED FOR PREVENTING MATERNAL-FETAL HIV TRANSMISSION

The Food and Drug Administration today approved the anti-AIDS drug AZT (zidovudine) for use in preventing transmission of HIV, the virus that causes AIDS, from HIV-infected pregnant women to their babies.

Data supporting the new indication comes from a federally sponsored study designed to determine whether AZT reduces the risk of passing the HIV virus from infected mothers to their infants either before or during birth.

In this randomized, placebo-controlled trial, HIV-infected women received 500 mg of AZT per day orally during pregnancy and a continuous intravenous infusion of AZT during labor. Therapy was begun between 14 and 34 weeks after conception. Newborns received oral AZT within 24 hours after birth and for six weeks thereafter. The study did not treat women during the first trimester of pregnancy. Also, women with prior use of AZT or CD4 counts below 200 were not eligible for the study.

The study was halted when a planned interim review of the data showed that for women treated with AZT the estimated rate of transmitting the virus to their babies was reduced by approximately

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two-thirds, from 25.5 percent infected babies from women on placebo to 8.3 percent infected babies from women on the AZT regimen. A long-term followup study of babies exposed to AZT is under way.

The drug was well tolerated by both mothers and infants. Side effects reported during the study included reversible mild anemia in some infants.

On July 28, FDA's Antiviral Drugs Advisory Committee reviewed the application to amend the AZT label and unanimously recommended that the agency approve this amendment.

With today's approval, AZT is now indicated for the prevention of maternal-fetal HIV transmission as part of a regimen that includes oral AZT beginning between 14 and 34 weeks of gestation, intravenous AZT during labor, and administration of AZT syrup to the newborn after birth.

AZT is manufactured by Burroughs Wellcome Co. of Research Triangle Park, N.C. and is marketed under the trade name Retrovir.

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